

**DAIDS Networks Conference Call**  
**August 14, 2003**  
**3:00pm EST/12:00pm PST**

**Draft Minutes**

**WELCOME AND INTRODUCTIONS:** Dr. Tramont welcomed the group and briefly summarized the goal of the Network Leadership calls as a forum to improve effectiveness and transparency by facilitating communication and network leadership in operations and policy.

Everyone on the call (DAIDS staff and Networks) introduced themselves and gave their affiliation.

**CONFERENCE CALL PROCESS:**

The Network calls will last one hour; it will start and end promptly on time. Dr. Tramont will end group discussion 15 minutes before the hour is up, to allow each participant to provide input or raise issues for future discussion in a round robin format.

**AUGUST 14 TOPICS**

**(a) Time and day for future conference calls/meeting**

- Future calls - third Wednesday of each month at 2:30 pm EST/11:30 am PST
- There will be a face-to-face meeting in NYC on September 17<sup>th</sup> before the AIDS Vaccine 2003 Conference at 5:30 (or 6pm) - 9:30 pm. Note: This meeting will be in place of a September call. The venue is yet to be determined but will likely be in the conference hotel. You will receive information as soon as possible.

**(b) CRO has been withdrawn**

- The DAIDS RFP for a CRO has been withdrawn for the moment allowing the network investigators to provide input in future decision-making. DAIDS will reissue the RFP for the CRO and award in FY 04
- The CRO is a broad based flexible support mechanism to enhance investigator-initiated research.

**Issue Raised on Expectations of CRO:** There is no expectation for CROs to provide academic/scientific expertise.

- CROs will add value especially in the international arena. Some examples discussed of roles that a CRO can play:
  - Provide long-term continuity if a PI detaches from the trial in some way, e.g. retires. It is especially necessary in the international community to have a mechanism in place to fulfill obligations.  
**Issue Raised on current SOP:** In the US there is infrastructure, training and processes in place to provide continuity since awards are made to the institutions. This allows DAIDS to work with these institutions and continue a trial if for some reason the PI does not continue. This does not currently exist in the international community.
  - If, for example, a vaccine does not protect against infection, but results in a change in viral setpoint, then we could be faced with very long-term follow up. CROs may provide the mechanism to provide such long-term follow up, perhaps for the duration of peoples' lives.
  - A CRO will provide an easier mechanism to move money around when necessary. For example, it is much easier to have a contractor issue a

subcontract to quickly provide resources, than it is to work through other funding mechanisms.

- A CRO can provide many types of infrastructural support that are not the strengths of academic institutions, e.g. IT infrastructure, certain types of training, assistance with financial accounting at the local institution, on-site quality assurance, etc.
- DAIDS would like feedback from networks on how network investigators think that a CRO can contribute and add value to their research.

**(c) All networks will be re-competed FY '06**

- All Networks will re-compete at or about same time allowing for more integration

***Issue Raised about PACTG inclusion:*** PACTG will be included

***Issue Raised on DEA workload:*** DAIDS is working with DEA to plan for the recompetition.

**(d) Feedback from Network participants.**

- Conference call minutes will be sent to participants for review and input
- Final minutes will be sent out to all network investigators.

**(e) Future Topics - For Discussion September 17<sup>th</sup>**

- Scientific goals for the next 5 years
- Collaboration/Integration of all networks in the global environment

Issues raised during the round robin segment of the meeting.

- *When addressing scientific goals, it is important to define what Networks want to prioritize and do as well as what they DO NOT want to do so that DAIDS can look for other mechanisms fulfill goals.*
- *In the international arena, it might be valuable to contract out laboratory support and coordinate with the networks.*
- *Get briefed on the activities and agendas of other organizations--specifically CDC. Dan and Alan for CDC will take the lead on this for a future call*
- *Collaboration with CDC and USAID in the international arena. For example in Zimbabwe they were working on lab tests for several NIH projects and were able to leverage learnings/resources from one to another.*
- *Agenda prepared in advance so folks can provide comments.*
- *Collaboration/synergy with CDC and DOD.*

## **ACTION ITEMS**

- Send out minutes ASAP
- September 17 face to face meeting - let Daniel Montoya know whether 5:30 or 6 pm will be more suitable based on travel plans and whether you will or will not be at the meeting [dcmontoya@niaid.nih.gov](mailto:dcmontoya@niaid.nih.gov)
- At the September Meeting be prepared to discuss:
  - Scientific goals for the next 5 years
  - Collaboration/Integration of all Networks in the Global Environment
- Provide feedback on utilization potential for a CRO.
- Dr. Tramont will follow up with a letter requesting specific information with regards to scientific goals